Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 18-30 are pending in the application, with 18, 22, 26, 29 and 31 being the independent claims. New claims 31-34 are sought to be added. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Rejections under 35 U.S.C. § 102

Claims 18, 19, 26, 27, 29, and 30 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,486,435 to Schmidt *et al.* ('435 patent). The Examiner asserts that the '435 patent teaches a free-flowing, non-agglomerated, non-caking vitamin powder composition comprising about 45 to about 60 percent vitamin, about 2 to about 18 percent of a water insoluble carrier, about 0.2 to about 2 percent hydrophobic silica, and other ingredients. The Examiner also asserts the '435 patent teaches that the water insoluble carrier can be corn starch, the vitamin can be selected from vitamin A, D, E, K and mixtures thereof as well as vitamin B1, B6, B2, B12, C and mixtures thereof, and that the vitamin composition is suitable for preparation of tablets. Office action at page 2.

Applicants have amended the claims in view of the Examiner's comments. Claims 18 and 26 have been amended to recite compositions comprising 65-80% vitamin. (Claim 19 is dependent upon 18; claim 27 is dependent upon claim 26; and claim 30 is dependent upon either 18 or 26).

MPEP § 2131 describes the application of 35 U.S.C.§ 102 (b). A claim is only anticipated if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP. § 2131 *citing Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). While only one reference should be used in making a rejection under § 102, the use of multiple references has been held to be proper when the extra references are cited to prove an enabling disclosure, explain the meaning of a term, or show that a characteristic that is not disclosed in the reference is inherent. *Id.*

Applicants contend that this rejection has been overcome by amending the claims to specify that the vitamin content in the composition is at least 65 to about 80%. The '435 patent does not expressly or inherently disclose a composition comprising at least 65% of a vitamin.

Claims 26-30 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,603,143 to Schmidt ('143 patent). The Examiner asserts that the '143 patent discloses vitamin active powders which are more free-flowing and stable than conventional vitamin powders. The Examiner then assets that the '143 patent also teaches the vitamin can be vitamin E and the fact that vitamin E comprises a group of natural substances known as tocopherols. The Examiner also assets that the '143 patent teaches that the silicon dioxide

used in the composition has a density of around 0.2 g/cc (which is equivalent to 12.5 lbs./cu. Ft.), and a particle size which passes through a 100 mesh sieve. Office action at page 3. Claim 26 was amended in view of the Examiner's comments. (Claims 27, 28, and 30 are dependent upon claim 26.)

Applicants contend that this rejection has been overcome by amending claim 26 to specify that the content of vitamin in the composition is at least 65 to about 80%. The '143 patent does not expressly or inherently disclose a composition comprising at least 65% vitamin. Applicants believe that claim 29, as amended by a preliminary amendment, is not anticipated by the '143 patent because claim 29 specifies a composition with a vitamin content of at least 65%.

Claims 18, 19, 26, 27, 29, and 30 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,234,695 to Hobbs *et al.* ('695 patent). The Examiner assets that the '695 patent discloses "a vitamin E composition comprising a free flowing powder containing a vitamin E compound, and at least one flow agent selected from silicon dioxide, starch and others". The Examiner also asserts that the '695 patent teaches that the vitamin E compound is present in between about 20-60%. Office action page 3.

Applicants contend that this rejection has been overcome by amending claims 18, 26 and 29 to specify that the content of vitamin in the composition is at least 65 to about 80%. The '695 patent does not expressly or inherently disclose a composition comprising at least 65% vitamin.

Rejections under 35 U.S.C. § 103

Claims 18-28 are rejected as being unpatentable over the '435 patent because it teaches a vitamin powder composition comprising silica, a vitamin, and corn starch. The Examiner then asserts that this reference teaches that the vitamin can be selected from a group including vitamin E. It is the Examiner's position that with respect to the particular silica particle size, absent a clear showing of criticality, the determination and manipulation of particular sizes is within the skill of the ordinary worker as part of the process of normal optimizations. The Examiner then shifted the burden to the applicant to show why the difference in particle size or surface area renders a different result. The Examiner concludes that one of ordinary skill in the art would have been motivated to make a vitamin composition comprising pitman E, silica, and corn starch, based on the teachings of the '435 patent with the expected result being a free-flowing powder, non-sticking powder useful for pharmaceutical formulations.

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. To establish a *prima facie* case, the courts have held that three criteria must be met: i) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings, ii) there must be a reasonable expectation of success, and iii) the prior art reference (or references when combined) must teach or suggest all the claimed limitations. MPEP. § 2142 citing *In re Vaeck*, 947 F.2d 488, 20 USPQ 2d 1438 (Fed. Cir. 1991).

Applicants respectfully request reconsideration of these claims in light of the amendments to the claims because there is no suggestion or motivation in the '435 patent to produce a composition that contains at least 65% vitamin. Furthermore, the '435 patent teaches away from concentrations of vitamin higher than 60%. "The non-agglomerated powders of the invention have the following composition on a dry basis: vitamin - about 45 to about 60% by weight, *preferably about 48 to about 55 percent* by weight". See column 4 lines 51-56.

Claims 22-30 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the '143 patent. The Examiner asserts that the '143 patent does teach that the particles are smaller than 150 microns notwithstanding the fact that it does not teach the specific particle size for the silica. The Examiner asserts that the determination of a particular particle size from within a broad range is within the skill of the ordinary worker as part of normal optimization. The Examiner also asserts that the '143 patent does not teach the surface area of the silica and that the burden is shifted to applicant to show that the silica disclosed by the '143 patent does not possess the same characteristics as the silica as claimed. Finally, the Examiner asserts that the '143 patent does not specifically refer to mixed tocopherol, however, this reference does teach that vitamin E is a group of natural substances known as tocopherol and further teaches that vitamin E can be used as the vitamin of the disclosed compositions. The Examiner then points to Applicants' specification which describes that vitamin E is a mixture of different molecular species which vary based on the natural variation in the oil. The Examiner adds that it would have been obvious based upon Applicants' specification that the disclosure in the '143 patent teaches the use of vitamin E

in the instant claims. The Examiner concludes that one of ordinary skill in the art would have been motivated to make a vitamin composition comprising vitamin E and silica and that the result would be a free-flowing, fat soluble vitamin powder with improved stability thereby rendering these claims *prima facie* obvious.

Applicants respectfully request reconsideration of these claims in light of the amendments because there is no suggestion or motivation in the '143 patent to produce a composition that contains at least 65% vitamin with silica having a particle size between 40-50 microns. The '143 patent teaches a composition comprising about 40 to about 60% vitamin E. See patent, column 6 line 34. One of ordinary skill in the art would not be led to use a smaller silica size, in view of the '143 patent, because it would be unexpected that the smaller size would impart improved stability.

Claims 18-30 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the '695 patent which the Examiner has cited for teaching a vitamin E composition comprising a free flowing powder containing between 20-60% of a vitamin E compound and at least one flow agent selected from a group including silicon dioxide and starch. The Examiner then asserts that it would have been within the skill of the ordinary worker as a part of the process of normal optimization to determine the density and surface area for the silica as claimed by the applicant.

Applicants argue that this rejection has been overcome by amendment specifying that the concentration of vitamin in the claimed composition is at least 65%. A composition comprising 65% of a vitamin is not taught in the '695 patent.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Jane Shershenovich
Attorney for Applicants
Registration No. 48,841

Date: 5/21/02

1100 New York Avenue, N.W.
Suite 600
Washington, D.C. 20005-3934
(202) 371-2600

Version with markings to show changes made

18. (Once amended) A composition comprising about 5 to about 34 weight percent redried cornstarch, silica and at least 65 to about 80 weight percent of at least one vitamin wherein said silica has a particle size of between 40 and 50 microns.

26. (Once amended) A composition comprising silica and at least one vitamin, wherein said vitamin is present in amounts from about [50] 65 to about 80 weight percent wherein said silica has a particle size of between 40 and 50 microns.